4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1182]

# Draft Joint Food and Drug Administration/Health Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft "Joint Food and Drug Administration/Health Canada--Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada." This draft Quantitative Risk Assessment (the draft QRA) includes an Interpretative Summary, a Technical Report, with Appendixes, and a risk assessment model. The purpose of the draft QRA is to evaluate the effect of factors such as the microbiological status of milk, the impact of cheese manufacturing steps, and conditions during distribution and storage on the overall risk of invasive listeriosis to the consumer in the United States or Canada of soft-ripened cheese. The draft QRA makes it possible to evaluate the effectiveness of some process changes and intervention strategies in reducing the risk of listeriosis. We are making the draft QRA available for public comment.

DATES: Submit either electronic or written comments on the draft QRA by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

## I. Background

Listeria monocytogenes (L. monocytogenes) is a widely occurring pathogen that can be found in agricultural and food processing environments. Ingestion of L. monocytogenes can lead to the development of listeriosis, with consequences that may include septicemia, meningitis, encephalitis, spontaneous abortion, and stillbirth. Epidemiological data show that listeriosis has one of the highest hospitalization rates and one of the highest case fatality rates among foodborne diseases in the United States (Ref. 1). Serious illness may occur in people considered to be more susceptible, such as the elderly, individuals who have a preexisting illness that reduces the effectiveness of their immune system, and pregnant women (Ref. 2).

The United States and Canada have experienced sporadic illnesses and outbreaks of listeriosis associated with the consumption of soft cheese. Both FDA and Health Canada--Santé

Canada continue to evaluate the safety of soft cheese, particularly soft cheese made from unpasteurized milk.

## II. Quantitative Risk Assessment

The draft QRA (Refs. 3 to 6) provides a science-based analytical approach to collate and incorporate available data into a mathematical model. It provides risk managers with a decision-support tool to evaluate the effectiveness of current and future interventions to reduce or prevent listeriosis from consumption of soft-ripened cheeses. The draft QRA also may be used to target risk communication messages, identify and prioritize research needs, and provide a framework for coordinating efforts with stakeholders. The draft QRA has undergone an independent external peer review consistent with the requirements in the Office of Management and Budget's "Final Information Quality Bulletin for Peer Review." FDA's response to the peer-review is available electronically on the FDA Web site (Ref. 7).

The draft QRA focuses on the sources of L. monocytogenes contamination, the effects of individual manufacturing and/or processing steps, and the effectiveness of various intervention strategies on the levels of L. monocytogenes in the product as consumed and the associated risk of invasive listeriosis. The draft QRA's scope is:

- Pathogen of concern: L. monocytogenes;
- Food(s) of concern: Camembert, as an example of soft-ripened cheese;
- Populations of interest: The general populations of the United States and Canada, and subpopulations identified as at-risk in both countries (i.e., pregnant women, immunocompromised individuals, and the elderly population);
- Endpoint of concern: Invasive listeriosis; and
- Risk metric: The probability of invasive listeriosis per soft-ripened cheese serving.

The draft QRA uses a quantitative approach, using mathematical and probabilistic modeling, to estimate the risk per serving of soft-ripened cheese (using Camembert cheese as an example) in both countries. The draft QRA tests the effects of some alternatives on those risks. The draft QRA uses data from the literature, from government nutrition surveys, from a specific survey on home storage time and temperature practices, and from specific expert elicitations. FDA invites comments that can help FDA and Health Canada--Santé Canada improve:

- The approach used;
- The assumptions made;
- The modeling techniques;
- The data used; and
- The clarity and the transparency of the draft QRA documentation.

When finalized, FDA intends to use this risk assessment (which is limited to one pathogen in one type of cheese), along with other information and scientific assessments that more comprehensively consider the different pathogens that can be present in all types of cheeses made from raw milk, in its reevaluation of the existing 60-day aging requirements for cheeses made with raw milk (e.g., 21 CFR 133.182(a)).

## III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

## IV. Electronic Access

The draft QRA is available electronically on the FDA Web site http://www.fda.gov/food/scienceresearch/researchareas/riskassessmentsafetyassessment/ and at http://www.regulations.gov.

## V. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at http://www.regulations.gov. (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Goulet, V., M. Hebert, C. Hedberg, et al., "Incidence of Listeriosis and Related Mortality Among Groups at Risk of Acquiring Listeriosis." Clinical Infectious Diseases, 54(5): 652-660, 2012.

2. Scallan, E., R. M. Hoekstra, F. J. Angulo, et al., "Foodborne Illness Acquired in the United States--Major Pathogens," Emerging Infectious Diseases, 17(1): 7-12, 2011.

3. U.S. Food and Drug Administration and Health Canada (2012). "Joint Food and Drug Administration/Health Canada--Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Draft Interpretative Summary." Accessible at http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm.

4. U.S. Food and Drug Administration and Health Canada (2012). "Joint Food and Drug Administration/Health Canada--Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Draft Technical Report." Accessible at http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm.

5. U.S. Food and Drug Administration and Health Canada (2012). "Joint Food and Drug Administration/Health Canada--Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Draft Technical Report Appendices." Accessible at http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm.

6. U.S. Food and Drug Administration and Health Canada (2012). "Joint Food and Drug Administration/Health Canada--Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Draft Risk Assessment Model." Analytica file. Accessible at http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm.

7. U.S. Food and Drug Administration and Health Canada (2012). "Joint Food and Drug Administration/Health Canada--Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Answer to the Peer Review." Accessible at

http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.

Dated: February 5, 2013.

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[FR Doc. 2013-02960 Filed 02/08/2013 at 8:45 am; Publication Date: 02/11/2013]